

## **REMARKS**

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

### **Summary of Telephone Interview**

Initially, Applicants wish to thank the Examiner, as well as Supervisory Patent Examiner Michael Meller, for the helpful comments they provided to Applicants' representative during the telephonic interview of August 13, 2008. During the interview, Applicants discussed potential claim amendments. Specifically, Applicants indicated that claims 1-7 would be cancelled, without prejudice, claim 8 would be amended to incorporate the limitations of claim 1, and new claim 9 would be added to correspond to previous claims 1, 2 and 8. The Examiners indicated that these amendments would overcome the indefiniteness rejection.

Applicants also discussed the obviousness rejection in detail. The arguments set forth in the interview, as well as additional comments based upon the Examiners' comments, are set forth in detail below.

Again, Applicants appreciate the helpful comments and suggestions provided by the Examiners during the telephonic interview.

### **Claim Amendments**

Claims 1-7 have been cancelled, without prejudice.

Claim 8 has been rewritten in independent form.

New claim 9 has been added to the application, and is directed to the limitations of previous claims 1, 2 and 8.

Therefore, no new matter has been added to the application by the above- discussed amendments.

**Rejection Under 35 U.S.C. § 112, Second Paragraph**

The rejection of claims 1 and 2 as being indefinite under 35 U.S.C. § 112, second paragraph has been rendered moot by the above-discussed claim amendments.

**Patentability Arguments**

The patentability of the present invention over the disclosure of the reference relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

**Rejection Under 35 U.S.C. § 103(a)**

The rejection of claims 1, 2 and 8 under 35 U.S.C. § 103(a) as being unpatentable over Inoue et al. (WO 00/24273) is respectfully traversed.

**The Position of the Examiner**

The Examiner takes the position that Inoue et al. teach Chinese medicine formulations as oral composition of jellies, made with hydrocolloids at 0.01-10wt%, locust bean gum (carob bean gum), carrageenan and xanthan gum. The Examiner admits that the reference does not teach the claimed concentrations. The Examiner further states that the reference teaches that each of the claimed ingredients is suitable for combination in a pharmaceutical composition, and thus one of ordinary skill in the art would [reasonably expect] that the claimed ingredients *could* be combined together to produce a single pharmaceutical product.

**Applicants' Arguments**

Applicants respectfully disagree with the Examiner's position for the following reasons.

**Reference relates to many uses of sucralose**

As acknowledged by the Examiners during the telephone interview with Applicants' representative, the Inoue reference relates to many possible uses of sucralose. This is evident by the first sentence of the abstract of the reference, which recites "[n]ovel utilization of sucralose

which is a high intense sweetener.” Additionally, the disclosure of Inoue et al. relates to foods, cosmetics and pharmaceuticals, and has lengthy discussions of many different types of formulations.

Specifically, Section I of the reference relates to Sweetening Compositions, i.e. (1) sweetening compositions comprising sucralose and at least one sweet substance (paragraphs [0025] – [0100]), (2) sweetening compositions comprising sucralose and gluconic acid or salt, milk serum mineral, etc. (paragraphs [0101]-[0129]), and (3) sweetening compositions comprising sucralose and soybean polysaccharide (paragraphs [0130] – [0138]).

Section II of the reference relates to masking unpleasant smell and taste in foods, i.e. (1) masking unpleasant smell of foods with sucralose (paragraphs [0162]-[0303]), and (2) masking unpleasant taste of foods with sucralose (paragraphs [0304]-[0336]). Within section II-2 of the reference, there are two distinct sections, the first relating to Galenical-Containing Compositions (this is the section of the reference which mentions Chinese medicines), and the second relating to Oral Compositions Containing Amino Acid/Peptide. It is important to note that Section II-2 **fails to even mention hydrocolloids**. Rather, this section of the reference merely discusses masking the unpleasant smell or taste of medicines, e.g., Chinese medicines, with **sucralose**.

Section III of the reference relates to Performance Food Compositions, i.e. (1) compositions comprising sucralose and hydrocolloid (paragraphs [0337] – [0377]), and (2) compositions comprising sucralose and starch (paragraphs [0378]–[0387]). This is the section of the reference which **finally** mentions hydrocolloids (although separately from the mention of Chinese medicines).

Chinese medicines of reference not in jelly form, nor with Applicants’ recited bases

Applicants acknowledge that paragraph [0309] illustrates Kakkon-to and Sho-saiko-to as Chinese medicines. However, **many** types of Chinese medicines are disclosed by the reference. Additionally, paragraph [0312] of the reference states, “[i]t is necessary to prepare the galenical-containing composition with **masked unpleasant taste** according to the present invention that the composition contains **sucralose eventually**.” (Emphasis added.) Further, paragraph [0314] states “[a]ccording to the present invention **the unpleasant taste** derived from galenicals can be

significantly **masked by adding sucralose**, and a drug with an improved flavor, taste and swallowing feeling can be prepared.” (Emphasis added.)

Thus, it is clear that the reference relies upon sucralose as a taste-masking agent, and **does not even contemplate a combination of bases, much less Applicants’ recited combination of bases**, for taste-masking. In fact, the reference teaches away from another taste masker, since the reference clearly indicates that sucralose is **necessary** for the taste-masking function.

Paragraph [0310] of the reference (which falls within the above-discussed section II-2, relating to foods with masked unpleasant taste) states that formulations of this type may be in any form, such as powders, granules, extracts, liquids, syrups. However, it is important to note that this paragraph **does not mention jelly**. Thus, although the portion of the reference which relates to Chinese medicines does provide several types of acceptable formulations, **this portion of the reference does not teach, or even mention, a jelly formulation comprising a Chinese medicine**.

Applicants note that this disclosure of the cited reference is consistent with the types of formulations discussed in the background section of Applicants’ specification. Specifically, Applicants disclose that these types of formulations (powders, granules, tablets and liquids) are known in an effort to mask unpleasant taste, but are **not desirable** because a large amount must be taken, leaving a sandy feeling in the mouth, or the bitter taste spreads in the patients’ mouth. (Please see page 1, line 23 to page 2, line 18 of Applicants’ specification.)

“Jellies” of reference not in combination with Chinese medicines

Applicants acknowledge that “jellies” are eventually *mentioned* in the reference, in paragraph [0328]. However, it is important to note that this disclosure is **in a separate section of the reference**, i.e., one **which discusses oral compositions containing amino acid/ peptide** (Section II-2-2).

Applicants discuss jellies in the background section of the specification, i.e. jellies using agar and gelatin. (Please see pages 2 and 3 of Applicants’ specification.) However, as shown in the Examples of Applicants’ specification, **gelatin and agar perform unexpectedly worse than Applicants’ recited base components**.

On the contrary, the disclosure of hydrocolloids in the reference (discussed in detail below) does not distinguish between different hydrocolloids. In fact, agar and gelatin (which are demonstrated as being inferior by Applicants) are included in a laundry list with carrageenan in the teachings of the reference.

Hydrocolloids in reference, not Applicants' recited combination,  
nor in combination with Chinese medicine

As mentioned above, Section III of the cited reference relates to performance food compositions. This is the section of the reference which finally mentions hydrocolloids.

Specifically, paragraph [0338] states that a viscous food composition may comprise at least one hydrocolloid selected from the group consisting of locust bean gum, carrageenan, etc. Applicants note that this portion of the reference employs the phrase "selected from the group consisting of", and fails to mention xanthan gum.

Separately, paragraph [0340] of the reference discusses that an emulsified food composition may comprise at least one hydrocolloid selected from the group consisting of xanthan gum, etc. Again, this passage of the reference employs the phrase "selected from the group consisting of", and fails to mention carob bean gum or carrageenan.

Further, **this discussion regarding hydrocolloids is completely unrelated to the discussion of Chinese herbal medicines.**

Many descriptions and examples in reference,  
yet none employ Applicants' recited combination of bases

None of the Examples relating to part II of the lengthy reference disclose a **jelly comprising a Chinese medicine, much less with Applicants' recited colloids**. [Part II of the reference is the section which discusses food with masked unpleasant taste using sucralose as masking agent for unpleasant taste, and is the section of the reference which mentions Chinese medicines.]

Example II-2-1(1) (paragraph [0724]) discloses a Japanese green gentian powder and Example II-2-1(2) (paragraph [0726]) discloses Saponin. Both of these examples relate to

Chinese medicines, however, each example only discloses the drug and sucralose, with an improvement in taste masking. Thus, neither example mentions a combination of a Chinese medicine with the three bases recited in Applicants' claims.

Under the subtitle "In Performance Food Composition", (paragraph [0337]) of the reference, there are the following descriptions regarding hydrocolloids:

In paragraph [0338], (1-1) A viscous food composition comprising sucralose and at least one hydrocolloid selected from the group consisting of **locust bean gum (carob bean gum)**,  **$\gamma$ -carrageenan** and soybean polysaccharides.

In paragraph [0339], (1-2) A gel food composition comprising sucralose and at least one hydrocolloid selected from the group consisting of **agar**, gellan gum, native gellan gum, **gelatin**,  **$\alpha$ -carrageenan**,  **$\iota$ -carrageenan**, **pectin**, tamarind seed polysaccharides, alginic acid, **alginic acid salts**, tara gum, furcellaran, and curdlan, in particular at least one hydrocolloid selected from the group consisting of **agar**, gellan gum, native gellan gum and  **$\kappa$ -carrageenan**.

In paragraph 340, (1-3) An emulsified food composition comprising sucralose and at least one hydrocolloid selected from the groups consisting of gum Arabic and **xanthan gum**.

Additionally, the following examples of foods are illustrated in the cited reference:

I-1-15: Ice cream containing **locust bean gum**, **carrageenan** and guar gum.

I-1-16: Tare for Boiled Eel containing **xanthan gum** and guar gum.

III-1-1(2): Soft Yogurt containing **locust bean gum**.

III-1-2(1): White Peach Jelly containing  **$\kappa$ -carrageenan**.

II-1-2(3): Cream Coffee Jelly containing **locust bean gum**, and  **$\kappa$ -carrageenan** and agar.

IV-7-1: Tare for Yakiniku containing **xanthan gum**.

V-2-9: Wrapping for Buns containing **xanthan gum**.

The descriptions and Examples of preparations employing carrageenan, carob bean gum or xanthan gum are illustrated above. However, notably, there is no preparation in the reference which employs a combination of carrageenan, carob bean gum and xanthan gum, even in foods.

### Showing of Unexpected Results

In Applicants' Declaration filed April 16, 2007, the following was demonstrated.

In Comparative experiment A, a composition (Sho-saiko-to) comprising carrageenan alone had much higher syneresis (separation of gel), and is thus inferior to a composition with carrageenan, carob bean gum and xanthan gum.

In Comparative experiment B, a composition (Kakkon-to) comprising carrageenan, carob bean gum and xanthan has superior performance with regards to syneresis compared to a composition comprising carrageenan and carob bean gum alone.

In Comparative Example C, the composition (Kakkon-to) containing carrageenan and carob bean gum, or containing carrageenan is inferior to a composition (Kakkon-to) containing caraggenan, locust bean gum and xanthan gum, with regards to syneresis.

**Thus, Applicants have clearly demonstrated, through a showing of unexpected and superior results, that the combination of bases recited in the claims is better than one of the bases alone, or a combination of two of the bases.**

Further, in Applicants' Declaration filed December 28, 2007, it was shown that a composition (Kakkon-to) containing pectin and agar, *in addition to* carrageenan, locust bean gum and xanthan gum (the composition disclosed in previously cited Fukui et al.) is far inferior with regard to syneresis, to a composition (Kakkon-to: Example 2) of the present invention, which does not contain pectin and agar.

Additionally, in Tables 4-1 and 4-2 of Applicants' specification, a composition (Kakkon-to) containing agar (Comparative Example 5) shows much stronger syneresis compared to compositions (Kakkon-to) of Applicants' invention, and thus the former composition is inferior.

Further, in Tables 6-1 and 6-2 of Applicants' specification, a composition (Seijo-bofu-to) containing sodium alginate (Comparative Example 7), a composition (Seijo-bofu-to) containing agar (Comparative Example 8), and a composition (Seijo-bofu-to) containing gelatin (Comparative Example 9) show very strong syneresis (and are thus inferior) compared to compositions (Seiko-bofu-to) according to Applicants' invention. [Applicants note that this comparison relates to composition comprising Seijo-bofu-to. However, Applicants include this discussion, since it further demonstrates the unexpected results of Applicants' recited

combination of bases.]

### Summary

Thus, as made evident by the comparisons discussed above, compositions comprising pectin, agar, gelatin or sodium alginate are far inferior to a composition according to Applicants' invention (with the three recited bases). Furthermore, it is also demonstrated that when any one or two compounds from carrageenan, locust bean gum and xanthan gum are omitted, syneresis on the compositions becomes strong, thus resulting in an inferior composition. Thus, Inoue et al. fails to teach or suggest Applicants' claimed composition.

Furthermore, even assuming, for the sake of argument, that the Examiner has presented a *prima facie* case of obviousness regarding Applicants' claimed composition, Applicants have clearly provided a showing of unexpected and superior results, which rebuts any showing purportedly made by the Examiner. MPEP 716.02(a)(II) states that "[e]vidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness. "

One or ordinary skill in the art would not make a composition with the three specific bases recited by Applicants based upon the cited reference, since the reference fails to provide any motivation to do so. The reference plainly fails to mention a combination of Chinese medicine with Applicants' three base components in a jelly form.

The reference cited by the Examiner is **74 pages long**. Applicants assert that it is untenable that **combining any combination of ingredients** from the reference would be obvious. The reference is clearly broken into distinct sections, and Applicants components are found in varying (and distinct) sections of the reference.

However, even if the Examiner maintains her position that the reference renders the combination of components obvious, the reference clearly fails to teach or suggest that Applicants' recited base system would result in masking unpleasant taste, better preservation, and less syneresis (breaking up of gel). In fact, the cited reference actually teaches away from Applicants' composition masking unpleasant taste, because the reference clearly relies upon sucralose for this purpose. Furthermore, in accordance with the MPEP, Applicants have



provided a showing of superior results.

Accordingly, for the above reasons, Applicants' invention is patentable over the cited reference, and the rejection set forth above should be withdrawn.

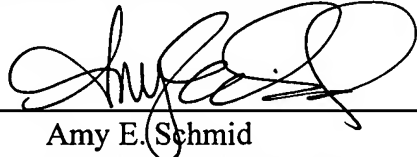
**Conclusion**

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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